Final On-Site Laboratory Evaluation Report (SDWA)

Inorganic Chemistry

(Rev. 10-15-09)

West Virginia Department of Health and Human Resources
Bureau for Public Health
Office of Laboratory Services
Environmental Chemistry Laboratory Section
4710 Chimney Drive, Suite G
Charleston, WV 25302

On-site: September 22-23, 2009

Surveyed by:

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A. Introduction:

On September 22-23, 2009 an on-site inspection of inorganic chemistry was conducted of the West Virginia Department of Health and Human Resources, Bureau for Public Health, Office of Laboratory Services located at 167 11th Avenue, South Charleston, West Virginia 25303-1137. The chemical analyses of drinking water samples are conducted at a separate location, Environmental Chemistry Laboratory Section, 4710 Chimney Drive, Suite G, Charleston, WV 25302. The purpose of this inspection was to determine the capability of the laboratory to perform its mission as it relates to the Safe Drinking Water Act (SDWA). The laboratory was represented by: Dr. Andrea Labik, Director; Charlotte Billingsley, Associate Director Office of Laboratory Services; Larry Duffield, Program Manager (Environmental Chemistry); Greg Young, Chemist (fluoride, chloride, sulfate, nitrate/nitrite, cyanide, Laboratory Information Management System); Patrick Marchio, Chemist (metals); Zachary Boyko, Chemist, (cyanide, fluoride, nitrate and nitrite); and Becky Payne, Laboratory Assistant (fluoride). This inspection was conducted by: Robin Costas, Chemist (evaluation of metals); George Long, Senior Environmental Employment Program Chemist (evaluation of inorganic non-metals); and Joseph Slayton, Senior Scientist (evaluation of inorganic non-metals and the quality system). The assessors represented the USEPA, Region III, Office of Analytical Services and Quality Assurance, located at 701 Mapes Road, Ft. Meade, Maryland 20755-5350.

- Though a number of samples for drinking water are from other than compliance monitoring (e.g., private drinking water wells), all samples are analyzed as if compliance samples.

- The laboratory lost the capability to perform the analyses of organic contaminants for SDWA in 1997. These analyses are performed by commercial laboratories certified by West Virginia. Efforts continue to regain this analytical capability as expertise in organic analyses would not only provide a valuable capability for the WV SDWA program, but also would improve WV's ability to oversee and certify laboratories for organic analyses. It was conveyed during this assessment that the Office of Environmental Health Services has recently funded the necessary equipment to support the analysis of trihalomethanes and haloacetic acids at the Environmental Chemistry Chimney Laboratory. The listing in Section F of this report, "Contaminant Method Information" is the listing of primacy drinking water analytes for which the principal state laboratory (PSL) requested SDWA certification, as part of the pre-survey questionnaire for this on-site assessment. The Region 3 Drinking Water Branch will be working with the WV Office of Environmental Health Services to secure copies of contracts and current SDWA certificates for commercial laboratories (certifications via the National Environmental Laboratory Accreditation Program), to cover the analytical areas not within the PSL's scope of certification.

- The OLS has recently purchased a new Perkin Elmer ELAN ICP/MS system which should

allow replacement of outdated equipment, improve analytical throughput, allow the expansion of analytical capabilities and provide first hand experience with mass spectral analyses. This experience will also be important for WV's certifications of commercial laboratories.

B. Personnel:

Since the last on-site assessment, one new chemist has been hired (Zachary Boyko). The courtesy and professionalism of the laboratory personnel was greatly appreciated by the inspection team.

C. Proficiency Testing (PT) Samples:

The laboratory results for Proficiency Testing samples for the years 2007 through 2009 were reviewed during the on-site evaluation (WS127, WS129, WS139, WS151, and 061809G from Environmental Resource Associates). The laboratory results were "Acceptable" for all regulated inorganic parameters reported.

D. Assessment Procedures/ Data Audit:

The assessment included interviews of analysts and managers, inspection of equipment and calibration materials and the review of records. The documents reviewed included: the laboratory Manual for QA (MQA) and technical SOPs; demonstration of capability and method detection limit performance studies; Proficiency Testing (PT) results and supporting data; recent internal audit reports; EPA's last on-site inspection report; and laboratory analytical reports (May 2006 and May 2005). The analytical records review traced the results from log-in records to the original instruments and other measurements to the final reported values.

E. Analytical Method References:

The list of parameters in Section E were audited during this inspection with the associated methodology cited as follows:

(SM) - Standard Methods for the Examination of Water and Wastewater, 18th- 21st ed.
(EPA83) - Methods for Chemical Analysis of Water and Wastes, EPA-600/4-79/83.
(EPA93) - Determination of Inorganic Substances in Environmental Samples, Aug 1993, EPA/600/R-93/100.
(EPA94) - Methods for the Determination of Metals in Environmental Samples, May 1994, EPA/600/R-94/111.
(CLADW) - Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance, January 2005, EPA 815-R-05-004.
(CLADW - Supplement) Supplement to the Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance, June 2008, EPA 815-F-08-006.

F. Contaminant Method Information:

Inorganic Contaminants (IOCs)	Methods	Instrumentation
Antimony	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Arsenic	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Asbestos	Not reviewed	Not reviewed
Barium	EPA94, 200.7	ICP, Varian Liberty 100
Beryllium	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Cadmium	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Chromium	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Copper	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Copper	SM 3111B	Flame, Varian SpectrAA - 400 Plus
Cyanide (free)	SM 4500-CN-F	Ion Selective Electrode Ion Selective Electrode, Orion Expandable IonAnalyzer EA 940, Orion Cyanide electrode 9406BN
Cyanide (total) *	Not reviewed	Not reviewed
Fluoride	EPA 300.0	Dionex- DX120 ion chromatography work station with AS-23 column, and 25µL sample loop
Fluoride	SM 4500-F-C	Ion Selective Electrode, ThermoOrion EA9409BN, 900100
Lead	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Mercury	EPA 245.1	CVAAS, Cetac QuickTrace M-6100
Nickel	Not reviewed	Not reviewed
Nitrate	EPA 300.0	Dionex- DX120 ion chromatography work station with AS-23 column, and 25µL sample loop
Nitrate	EPA 352.3	Automated Cadmium Reduction, Technicon Analyzer II
Nitrate and Nitrite (total)	EPA 352.3	Automated Cadmium Reduction, Technicon Analyzer II
Nitrite	EPA 300.0	Dionex- DX120 ion chromatography work station with AS-23 column, and 25µL sample loop
Nitrite	EPA 352.3	Automated Cadmium Reduction, Technicon Analyzer II
Selenium	SM 3113B	GFAAS, Varian SpectrAA - 400 Plus
Sodium	SM 3111B	Flame AA, Varian SpectrAA - 400 Plus
Thallium	Not reviewed	Not reviewed

* Total Cyanide is not utilized by WV's Office of Laboratory Services to screen for free cyanide and therefore is not a primacy parameter.

G. Calibration & Detection Information:

This table summarizes the mandated Maximum Contaminant Levels (MCLs) and laboratory's determined Method Detection Limits (MDLs), Minimum Reporting Limits (MRLs). The required relationship is as follows: MCL>MRL>MDL.

Inorganic Contaminants (IOCs)	**Calibration Standards (mg/L)**	**MCL (mg/L)**	**MCL (ug/L)**	**MRL (ug/L)**	**MDL (ug/L)**
Antimony	BLK; 0.003; 0.006; 0.012.	0.006	6	3	1.22
Arsenic	BLK; 0.002; 0.005; 0.010; 0.020.	0.010	10	2	.38
Asbestos	Not reviewed.	7 MFL	-	-	-
Barium	BLK; 0.005; 5.0; 10.0.	2.00	2000	5	0.0005
Beryllium	BLK; 0.0002; 0.0005; 0.001; 0.002.	0.004	4	0.2	0.03
Cadmium	BLK; 0.001; 0.002; 0.004	0.005	5	1	0.10
Chromium	BLK; 0.001; 0.0025; 0.005; 0.010.	0.100	100	1	0.48
Copper (GFAAS)	BLK; 0.001; 0.0025; 0.005; 0.010.	1.3*	1300	1	0.19
Copper (Flame)	BLK; 0.025; 0.050; 0.1; 0.5; 1.0.	1.3*	1300	25	0.004
Cyanide (free)	BLK; 0.05; 0.1; 0.2; 0.3; 0.4.	0.2	200	50	4
Cyanide (total) *	Not Reviewed.	0.2	200	-	-
Fluoride (IC)	SOP: BLK; 0.1; 0.2; 0.50; 1.00; 2.00. Actual: BLK; 0.4; 1.0; 2.0; 3.0; 4.0.	4.0	4000	400 Actual	17
Fluoride (ISE)	BLK; 0.050; 1.00; 3.00; 5.00.	4.0	4000	50	25
Lead	BLK; 0.001; 0.0025; 0.005; 0.010.	0.015*	15	1	0.17
Mercury	BLK; 0.0002; 0.0005; 0.001; 0.002; 0.005; 0.010.	0.002	2	0.0002	.000006
Nickel	Not reviewed.	Monitoring **	-	-	-
Nitrate (IC)	SOP: BLK; 0.1; 0.2; 0.50; 1.00; 2.00. Actual: BLK; 0.4; 1.0; 2.0; 3.0; 4.0.	10	10,000	400 Actual	7.2
Nitrate (TAA)	BLK; 0.05; 0.10; 0.25; 0.50; 1.00.	10	10,000	50	5
Nitrate &	BLK; 0.05; 0.10; 0.25;	10 with	500	50	3

Inorganic Contaminants (IOCs)	Calibration Standards (mg/L)	MCL (mg/L)	MCL (ug/L)	MRL (ug/L)	MDL (ug/L)
Nitrite(Total) (TAA)	0.50; 1.00.	Monitoring Trigger of 0.50			
Nitrite (IC)	SOP: BLK; 0.1; 0.2; 0.50; 1.00; 2.00. Actual: BLK; 0.4; 1.0; 2.0; 3.0; 4.0.	1	1,000	400 Actual	4.6
Nitrite (TAA)	BLK; 0.05; 0.10; 0.25; 0.50; 1.00.	1	1,000	50	6
Selenium	BLK; 0.002; 0.005; 0.010.	0.050	50	2	0.4
Sodium	BLK; 2.0; 5.0; 10.0; 15.0; 20.0.	20.0+	20000	2000	70
Thallium	Not reviewed.	0.002	2	-	-

* "Action Level".
+ "Recommended Level".
** No MCL, but monitoring required.

H. Quality Control (QC) Procedures & Accolades:

The laboratory follows a " Manual of Quality Assurance for Environmental Chemistry Laboratory and Environmental Microbiology Laboratory", (MQA, Rev. 2009). This document includes: a QA plan and policy statement; laboratory organizational chart; employee job descriptions; list of standard operational procedures; WV certified analyses for drinking water (groups); order form for sample bottles; sampling instructions; sample handling procedures; reporting of results; chain of custody (formal internal tracking is limited to cases which may involve litigation); quality assurance monitoring; analytical procedures; data reduction; data verification; data validation; data reduction, validation, reporting and storage; preventive maintenance; internal quality control and corrective action; precision and accuracy samples; proficiency testing; quantitative verification check with each batch of samples; and acronyms and definition of terms.

A partial list of the QC procedures observed during this inspection included: on-going temperature records of refrigerators and drying ovens; analysis of an external (2^{nd} source) QC sample with each analytical batch; routine digestion and analysis of a blank spiked at the reporting level, method detection limit determinations; duplicate analysis (precision measure); spike analysis (accuracy/recovery measure); blank analysis per batch; check standards (instrument performance checks) at beginning, end and 10% frequency (instrument drift measure); cadmium column reduction efficiency determination and recorded; use of standard weights to verify balance performance; on-going compilation and charting of QC check results; the recording of resistance/conductivity of the laboratory pure water each day of use; and the verification of electronic temperature monitoring devices quarterly. It was apparent from the extensive quality control procedures, that the laboratory personnel are dedicated to achieving

analytical excellence.

I. Analytical Deviations:

Deviations (findings) are those laboratory techniques not in compliance with the mandatory requirements of the reference analytical methods cited above, with the CLADW or 40 CFR Parts 141 and 142 requirements, or with the laboratory's quality system. The following changes are required for the laboratory to be in compliance with the SDWA program (reference/s are listed with each item).

Office of Laboratory Services Manual of Quality Assurance for Environmental Chemistry Laboratory and Environmental Microbiology Laboratory, 2009 (MQA)

Note: The needed additions to the quality system can be included in technical or administrative SOPs and not necessarily directly in the MQA.

1. The quality system needs to more fully describe sample log-in regarding checking of sample preservation (e.g., pH, temperature and residual chlorine). This needs to include in general terms who is responsible, how is it to be done and how/where this is recorded, CLADW 8.1, p. IV-9.

2. The quality system needs to describe the sample numbering system/s for both chemistry and microbiology and indicate exactly how SDWA compliance samples are uniquely labeled/identified, CLADW 8.5, P. IV-9.

3. The procedures for preparing of sample containers and assuring the quality of preservative materials employed are not described in the quality system. This description needs to include where this information is documented, CLADW 8.1, p. IV-9, CLADW 6, p. IV-3.

4. The quality system needs to address the traceability of calibrations to a national standard whenever applicable, CLADW 7.1.6, p. IV-5.

5. The quality system needs to provide a specific reference for the rounding rules used by the laboratory, CLADW 7.1.2, p. IV-4.

6. The quality system needs to specify the reporting of time of analysis to customers on the reporting forms for analyses with short holding times, e.g., <72 hours, CLADW 8.5, p. IV-9.

7. The quality system needs to describe the records system/s in more detail, e.g., location and organization of official records (job descriptions, training records, customer reports, demonstrations of capability, notebooks, certificates of analysis), who is responsible, how long they are maintained, how and where the records are archived and how are they protected/secured, CLADW 8.1, p. IV-9.

8. The quality system needs to describe the laboratory's data integrity policies and procedures, e.g., ethics policy, ethics training, confidential reporting of concerns, consequences of unethical activities, CLADW Supplement 1, p. 5.

9. The quality system needs to describe the quality system for the Laboratory Information Management System (LIMS). The following are taken as required topics to fulfill CLADW Section 8.1, page IV-9. The QA Plan and/or SOPs need to describe the policies and procedures used by the facility for record integrity, retention and storage:

9.1 Define the roles and responsibility in assuring data integrity of the LIMS.

9.2 Define the roles of other staff in monitoring the function and procedure (including maintenance) of the LIMS. The latter should be independent of LIMS personnel, report directly to laboratory management. This needs to include periodic audits to ensure integrity.

9.3 Have documented procedures and practices to verify the accuracy of LIMS raw data including the individuals responsible for entering data.

9.4 Have documented procedures for testing and quality assurance of hardwared and software, including procedures for tracking software versions and records of verifications.

9.5 Have documented security procedures to protect LIMS data.

9.6 Have documented procedures for testing, inspecting and maintaining new LIMS hardware.

9.7 Have documented procedures to assure the retention of laboratory records that comply with regulations (CLADW specifies record retention of at least 5 years for lab records and 6 years for inspection records). For example, the procedures for backing up the LIMS including who is responsible, the frequency, procedures and where this is documented.

9.8 Have documented listing of facility requirements for the LIMS.

10. The demonstration of capability study records need to include a copy of certificates for the second source material to further document the source and concentration. Also, the MDL studies need to list the Student-t value, CLADW 8.5, p. IV-9, 7.1.2, p. IV-4.

11. The quality system needs to define the calculation of relative percent difference (RPD) and relative standard deviation (RSD), CLADW 8.5, p. IV-9.

12. The quality system does not address laboratory pure water. The procedures, frequency of checks, who is responsible and where the results are recorded needs to be described.

Metals

1. If the lab decides to continue requiring annual MDL verifications, they must be completed as soon as possible (as per SOPs).

2. Volumes of the auto-pipet dispensers needs to be verified on the same basis as the manual pipets (as per the MQA).

Inorganic-Non Metals

EPA Method 353.2 for Nitrate, Nitrite and Total (Nitrate +Nitrite)

1. SDWA samples for total nitrate are routinely analyzed and reported as a sum for (NO2+NO3)-N. A concentration of 10 mg/L is used as a "trigger" for the re-sampling and re-analysis for nitrite and nitrate separately. The concentration for repeat monitoring actions must be lowered to 0.5 mg/L (1/2 the MCL for nitrite) as per the CLADW, Table IV-7 p. IV-27. Clarification on whether 0.5 mg/L is only required for new PW Supplies where as for on-going compliance monitoring 10 mg/L is acceptable was received from Michele Hoover (215-814-5258) in a 9/27/09 E-mail message. The message read: "...for WV, if combined NO3+NO2 test method is used after the initial monitoring and if the results is >=0.5 mg/L, systems need to analyze nitrite separately.

2. The SOPWET0300, rev. 2 needs to be corrected to indicate the addition of dechlorinating reagent and not sodium hydroxide. Also the SOP needs to include a reference for the procedures used for dechlorinating samples (a fixed concentration of agent) and where this step is to be documented, CLADW 11.3, p. III-5, EPA 353.2.

3. The laboratory reporting sheets (results provided to customers), includes the date of analysis but not the time of analysis. To help verify that holding times are met for nitrate and nitrite the time of analysis needs to be recorded, CLADW, 8.5, P. IV-9.

4. The MDL for Greg Young was dated 2003 and needs to be repeated as the SOP specifies that MDLs are to be repeated each year, SOPWET00300, Section 5.2.5.

4500-F-C, Fluoride by Ion Selective Electrode

1. The demonstration of performance study files need to be updated to include the "Unknown Analysis Data Summary", MQA, XVI.

2. The fluoride DOC study needs to list the source of the control limits, CLADW Section 7.1.2,p. IV-4 and Section 8.5, p. IV-9.

3. The final reports for the customer lists the MRL as 0 mg/L and values less than the lowest calibration standard were reported (0.5 mg/L). The customer report from LIMS needs to be corrected to show the actual MRL (0.5 mg/L) and report values less than the MRL as <0.5 mg/L, as per SOP Fluoride2009SOP, Section 9.

4. The QC Data Summary log templates need to include the units (e.g., % recovery), CLADW Section 8.5, p. IV-9.

5. Efforts need to continue to convert the current reporting form for fluoride analysis to the form as specified by the quality system, MQA, Section VIII, p. 60.

Support Equipment (Analytical Balances, Thermometers, Pipets, Laboratory Pure Water)

1. SOPWET01100, April 24, 2009 needs to be updated to include the recording of the serial numbers of the reference weights as part of the documentation of the verification of balance

operations, CLADW 8.5, p., IV-9, CLADW 11.3, p. III-4.

2. SOPWET01100, April 24, 2009 needs to be updated to include the requirement to calibrate electronic thermometers quarterly and that the documentation of thermometer verifications needs to include the type of thermometer (partial or full immersion and electronic/thermistor), CLADW 8.5, p., IV-9.

3. SOPWET01100 (April 24, 2009) needs to be updated to include the acceptance limits for mechanical pipet verifications, CLADW 7.1.2, p., IV-4.

Method 300.0, Ion Chromatography

1. Strike-outs on the lab sheets e.g., MDLs, and IDCs need the initials of the person who has made the correction, MQA, XIII, 2, paragraph 4.

2. The MDL by Zachary Boyko (series beginning 6/10/08 and lasting three days) had the wrong average of the three separate MDL runs and this needs to be corrected, SOPWET00200, method 300.0, section 5.2.4.

3. The calibration standards for the Fluoride MDL were 0.4, 1.0, 2.0, 3.0, and 4.0 mg/L while the SOP lists calibration standards as 0.1, 0.2, 0.5, 1.0, and 2.0 mg/L. The rationale for the change needs to be documented in SOPWET00200, EPA 300.0, section 4.3.12.

4. The SOP, SOPWET00200, method 300.0, section 7.6.1 describes using a 75µL injection loop when in fact, the analyst is using a 25µL loop. Likewise the laboratory is using an AS 23 column and not an AS14A as listed in the SOP section 4.1.1. The SOP needs to accurately list the procedures and equipment employed, MQA Section II.

Method 4500-CN-F, Ion Selective Electrode for free Cyanide

1. Strike-outs are not initialed, MQA XIII, 2, paragraph 4.

2. The Cyanide double junction fill solutions were dated 2006. The certificate for the material states that the solutions are only good for 2 years. Therefore the solutions are outdated and need to be replaced, SOPWET00600secttions 4.4.4 and 4.4.5.

J. Recommendations:

The following <u>suggestions</u> are offered for continuous improvement.

Metals (General)

a. Laboratory/Instrument duplicates are not required, except for 3113B. To help focus resources, it is suggested that the laboratory analyze one duplicate per 10 or 20 samples instead of every sample.

b. The adjustment of reagents, etc., to account for the 2 mL preservative is most likely an insignificant adjustment. It is suggested that the lab look into dropping this practice to help simplify processes. At this concentration level, nitric acid concentrations are not critical to accurate analysis.

c. There is no requirement to analyze the LFM twice. It is suggested that the lab use the laboratory/instrument duplicates to confirm stability. If the lab continues to analyze both the MSK and MDUP for mercury, SOP section 5.4.4 needs to be clarified to explain that these are instrument duplicates and not digested duplicates.

d. The Appendix A – QC Limits and Corrective Action Summary for each SOP is an excellent tool. It is suggested that the required frequency of analysis be added to this summary. In some of the SOPs it is a little difficult to find all of the QC information because it is spread out among several sections.

e. There is no requirement to run a digested fortified blank every batch. One option to save time would be to digest and analyze this QC check on some periodic basis, i.e., annually or quarterly. The CLADW says to run the MRL with each batch, but, doesn't require that it be digested.

f. Several SOPs list the acceptance limit for the correlation coefficient as greater than 0.995. It would be accurate to state that the limit is equal to or greater than 0.995, (200.7, 3113B, 3111B).

g. Section 6.2 of the 3111B SOP is a very good summary of the Data Analysis requirements for this method. It is suggested that something similar to this be added to the rest of the SOPs.

h. A table or chart should be developed which can be used to track the expiration dates of the second source standards so they can be re-ordered before expiration.

EPA 200.7

a. Instead of analyzing the QCS 3 times, it is acceptable to use the RSD result of the internal burns from one analysis as long as it is documented.

b. Section 6.8 of the SOP states that the LDP is analyzed after every 10 samples. If the lab decides to continue analyzing this on every sample, this section should be changed to reflect the actual practice.

EPA 245.1

a. The digestion log should be updated to include the LRBs and LFBs for each batch.

b. The temperature of digestion should be recorded to one decimal to more accurately reflect the $\pm$2 degree acceptance range.

c. It is suggested that the acceptance limits for the Calibration Blanks and the Preparation Blank be changed to less than the MRL. There is no requirement in the method that it be less than the

MDL. Since the lab does not report down to the MDL, it would be appropriate to adopt the CLADW suggestion that the blanks should not exceed the MRL (section 7.2.5).

SM 3113B

a. It is suggested that the acceptance limits for the QC Blank (Calibration Blank) and the Lab Reagent Blank be changed to less than the MRL. There is no requirement in the method that it be less than the MDL or IDL. Since the lab does not report down to the MDL, it would be appropriate to adopt the CLADW suggestion that the blanks should not exceed the MRL (section 7.2.5).

b. Since the furnace is on its way out, it is suggested that the extensive QC requirements be scaled back to the minimum acceptable items to allow more time for the analyst to spend on ICP-MS method development. One idea is to remove the practice of spiking the second instrument duplicate if it is less than the reporting level.

c. The next time a tube fails during a run, it is suggested that a check of the entire calibration range be done and not just with the mid-range standard and blank.

SM 3111B

a. SOP section 4.4.3 specifies that the QCS sample is analyzed at least quarterly. This should be changed to reflect the actual practice of analyzing it per batch.

b. SOP section 4.12.2 states that the LDP is analyzed after every 10 samples. If the lab decides to continue analyzing this every sample, this section should be changed to reflect the actual practice.

c. It is suggested that the acceptance limits for the QC Blank and the Lab Reagent Blank be changed to less than the MRL. There is no requirement in the method that it be less than the MDL or IDL. Since the lab does not report down to the MDL, it would be appropriate to adopt the DW Manual suggestion that the blanks should not exceed the MRL (section 7.2.5).

Inorganic Non-metals

Method 4500-CN-F

a. There is an obvious typo in SOPWET00600, sections 6.4.3 and 6.6.3 (tables). The word "sock" NaOH must mean "stock" NaOH.

b. The IDC dated 10/29/08 by Zachary Boyko lists the concentration of the fortified reagent as "0.05µg/L [NO3]". This should read "CN".

Support Equipment

a. SOPWET01100, April 24, 2009 needs to be updated to include checking that the analytical

balance is level.

Fluoride (ISE)

a. The QC limit table from the SOP should be added to the QC Corrective Action Table for ease of reference.

b. The wording of the SOP should be change to indicate that the electrode/s will be changed when needed (routinely 3-6 months).

c. Given this is a new analytical area, an internal audit should be considered for the ISE fluoride analyses.

Global Laboratory Suggestions

a. The QAO/s position/s should be independent of laboratory management.

b. Consideration should be given to determining MDLs based on analysis of a total of seven replicates on three separate days (e.g., 2 performed on one day, 2 more determined another day and 3 more determined the final day). This should not include selecting a subset of replicates, i.e., as per the provided example only 2, 2 and 3 would be performed each set (not seven each run). This suggested approach may increase the variance and result in a more accurate/realistic MDL determination than that obtained from averaging the variances from three separate sets.

c. The service visits for the analytical balances should be documented on the Balance Calibration Verification sheets/notebook.

d. As part of the records management system notebook, PT, IDC, MDL, QM, sample data file, etc., should be assigned a unique number and an effective date.

e. Efforts should continue to store quality system files in electronic format, e.g., MDL, DOC, unknown analyses. Consideration should be given to the purchase of a high speed scanner.

f. 10% of analytical data should be reviewed by a peer in addition to the current practice of only reviewing of results that exceed MCLs.

g. The quality system needs to require that technical SOPs include the MQA as a reference in all technical SOPs.

h. The frequency of QA Committee meetings should be specified in the quality system. This could include the statement that meetings are only held if there are important issues to address.

i. The frequency of internal audits should be set in the quality system, e.g., initially in a new area and for any analytical area having on-going QC problems.

j. The accuracy of volumes dispensed by mechanical pipets are checked each year. It is

suggested that this be increased to quarterly.

k. The MQA should specify a fixed format for SOPs. Also, the list of topics to be included in SOPs should be specified as required (i.e., "must" not "should"), and if any of the specified topics are not applicable that this could be noted as such in the SOP/s. The listing of required topics should be expanded to include "pollution prevention" and "safety".

l. The term "unknown" is used in the quality system and this term should be defined, i.e., second source for which the analyst does not know the true value.

m. The MQA should specify that SOPs are reviewed annually or with significant change and revised as needed.

n. The MQA, (e.g., p. 81), includes the terms "section lead" and " QA monitoring system". It is suggested that these terms be better defined.

o. It is suggested that the "Data Reduction" section of the QMA (p. 88) defer to the technical SOPs.

p. It is suggested that the data validation section of the MQA include insuring that the customer's data quality needs were met (method, MRL, etc.).

q. It is suggested that the significant figure section on p. 89 of the MQA defer to the technical SOPs.

r. It was noted that the LAN and E-mail service to the laboratory was very slow and adversely impacting efficiency of operations. The source for the problem should be determined (e.g., cable capacity) and corrected.

s. Efforts should continue to have more technical training for analysts, e.g., vendor seminars, APHA on-line training, etc.

t. Given the findings regarding differences in actual procedures and those listed in the SOPs, it is suggested that all analysts read and sign final versions of technical SOPs for the tests they perform.

K. Recommended Certification Status:

Based upon this on-site assessment and upon submission of acceptable corrective actions to address the findings listed above, the assessment team recommends the following SDWA certification status:

LEGEND

C – Certified
PC - Provisionally Certified
IC - Interim Certified

NC - Not Certified

Inorganic Contaminants (IOCs)	On-Site Certification Status	Method
Antimony	C	SM 3113B
Arsenic	C	SM 3113B
Asbestos	NC	Not Reviewed
Barium	C	200.7, EPA94
Beryllium	C	SM 3113B
Cadmium	C	SM 3113B
Chromium	C	SM 3113B
Copper	C	SM 3113B
Copper	C	SM 3111B
Cyanide (free)	C	SM 4500-CN-F
Cyanide (total)	NC	Not Reviewed (Not used for screening)
Fluoride	C	EPA 300.0
Fluoride	C	SM 4500-F-C
Lead	C	SM 3113B
Mercury	C	EPA 245.1, EPA94
Nickel	NC	Not Reviewed
Nitrate	C	EPA 300.0
Nitrate	C	EPA 352.3
Nitrate and Nitrite (total)	C	EPA 352.3
Nitrite	C	EPA 300.0
Nitrite	C	EPA 352.3
Selenium	C	SM 3113B
Sodium	C	SM 3111B
Thallium	NC	Not Reviewed

L. Inspectors:

Robin Costas 10/15/09

George Long 10/15/09

Joseph Slayton 10/15/09